

GLAXO INC -- ZOFTRAN ONDANSETRON HYDROCHLORIDE TABLETS --

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Product Identification
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Product ID:ZOFTRAN ONDANSETRON HYDROCHLORIDE TABLETS
MSDS Date:12/19/1994
FSC:NIIN:Submitter:F BT
Status Code:A
MSDS Number: CJGGK
=== Responsible Party ===
Company Name:GLAXO INC
Address:5 MOORE DR
City:RESEARCH TRIANGLE PARK
State:NC
ZIP:27709
Country:US
Info Phone Num:919-248-2100/2700
Emergency Phone Num:919-248-2100
CAGE:34006
=== Contractor Identification ===
Company Name:GLAXO WELLCOME INC.
Address:5 MOORE DR
Box:13398
City:DURHAM
State:NC
ZIP:27709
Country:US
Phone:919-248-2100
CAGE:34006

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Composition/Information on Ingredients
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Ingred Name:ONDANSETRON HYDROCHLORIDE
CAS:103639-04-9

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Hazards Identification
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Routes of Entry: Inhalation:YES Skin:NO Ingestion:YES
Health Hazards Acute and Chronic:INHALATION: MAY CAUSE ALLERGIC SENSITIZATION. EYES: SEVERE IRRITANT. INGESTION: MAY RESULT IN A VARIETY OF ADVERSE EFFECTS. ZOFTRAN TABLETS ARE INTENDED FOR MEDICAL USE TO PREVENT NAUSEA & VOMITING ASSOCIATED W/INITIAL & REPEATED COURSES OF CANCER CHEMOTHERAPY & ALSO WHEN ACCOMPANYING RADIOTHERAPY FOR CANCER.
Effects of Overexposure:IRRITATION, HEADACHE, SKIN RASH, CONSTIPATION, ABDOMINAL PAIN, WEAKNESS, CHANGES IN HEART RATE, ELECTROCARDIOGRAM, CHEST PAIN, DRY MOUTH, RARE BRONCHOSPASM, WHEEZING, ANAPHYLAXIS, SHORTNESS OF BREATH, UNCONSCIOUSNESS, CONVULSIONS, SHOCK.
Medical Cond Aggravated by Exposure:INDIVIDUALS KNOWN TO BE HYPERSENSITIVE TO ONDANSETRON HYDROCHLORIDE. PERSONS W/LIVER DISEASE.

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First Aid Measures
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First Aid:EYES: FLUSH W/LARGE AMOUNTS OF COOL WATER FOR 15 MINS. SKIN: WASH W/SOAP & WATER. INHALATION: IF NOT BREATHING, GIVE CPR/OXYGEN IF NECESSARY. INGESTION: IF AWAKE & ABLE TO SWALLOW, RINSE MOUTH W/WATER . NEVER GIVE ANYTHING BY MOUTH IF UNCONSCIOUS/HAVING CONVULSIONS. OBTAIN MEDICAL ATTENTION IN ALL CASES.

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Fire Fighting Measures
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Extinguishing Media:WATER SPRAY, MULTI-PURPOSE DRY CHEMICAL
Fire Fighting Procedures:WEAR FULL PROTECTIVE CLOTHING & USE SELF CONTAINED BREATHING APPARATUS.
Unusual Fire/Explosion Hazard:BREAKAGE OF TABLETS, IN BULK OPERATIONS, COULD CONTRIBUTE TO DUST FORMATION. AS W/ANY ORGANIC DUST, THERE IS POTENTIAL FOR EXPLOSION WHEN HIGH CONCENTRATIONS ARE SUSPENDED IN AIR.

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Accidental Release Measures
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Spill Release Procedures:PROTECTIVE EQUIPMENT MAY BE NECESSARY. FOR SMALL QUANTITIES, COLLECT LEAK & TRANSFER TO A WASTE CONTAINER FOR DISPOSAL. LARGE/DRIK QUANTITIES COLLECT BY CAREFULLY

DISPOSAL. LARGE/BULK QUANTITIES, COLLECT BY CAREFULLY SWEEPING/WIPING & PLACE IN A LABEL LED, SEALED CONTAINER FOR DISPOSAL. WASH AREA (FLOOR & OTHER CONTACT SURFACES) THOROUGHLY W/SOAP & WATER.

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Handling and Storage
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Handling and Storage Precautions:STORE BETWEEN 36 & 86F. PROTECT FROM EXCESSIVE MOISTURE.

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Exposure Controls/Personal Protection
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Respiratory Protection:RESPIRATORY PROTECTIVE EQUIPMENT SHOULD BE WORN WHEN WORKERS ARE EXPOSED TO HIGH DUST LEVELS. RECOMMENDATIONS FOR RESPIRATOR SELECTIONS IS NIOSH (ANSI Z88.2.

Ventilation:PROVIDE GOOD GENERAL EXHAUST VENTILATION.

Protective Gloves:IMPERMEABLE/LATEX

Eye Protection:REQUIRED

Other Protective Equipment:PROTECTIVE CLOTHING

Work Hygienic Practices:REMOVE/LAUNDER CONTAMINATED CLOTHING & SHOES BEFORE REUSE. WORK SURFACES SHOULD BE PROPERLY CLEANED/DISPOSED OF AFTER USE. A SUITABLE SOLVENT SUCH AS SOAP & WATER SHOULD BE USED FOR CLEANING.

Supplemental Safety and Health

WASH HANDS & OTHER AREAS OF SKIN CONTACT THOROUGHLY AFTER HANDLING THIS MATERIAL.

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Physical/Chemical Properties
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Appearance and Odor:4 MG WHITE/8MG YELLOW, OVAL TABLET ENGRAVED W/"4" / "8" & GLAXO; ODORLESS

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Stability and Reactivity Data
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Stability Indicator/Materials to Avoid:YES

Hazardous Decomposition Products:THERMAL DECOMPOSITION OF ONDANSETRON HYDROCHLORIDE: OXIDES OF NITROGEN & HYDROCHLORIC ACID.

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Toxicological Information
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Toxicological Information:SOME PATIENTS (5%) TREATED INTRAVENOUSLY W/ZOFRAN WHILE ALSO TAKING ANTI-CANCER MEDICATION HAD BRIEF & REVERSIBLE ELEVATIONS IN THE CIRCULATING LEVEL OF TWO ENZYMES. THERE ARE REPORTS OF LIVER FAILURE & DEATH IN CANCER PATIENTS RECEIVING ONDANSETRON IN COMBINATION W/TOXIC ANTICANCER DRUGS. WHETHER ZOFRAN CONTRIBUTED TO THIS PROBLEM IS UNCLEAR. THERE IS NO INDICATION THAT ONDANSETRON CAUSES CANCER/ MUTATION/BIRTH DEFECTS/OTHER REPRODUCTIVE HEALTH EFFECTS IN STANDARD TESTS. IN THE OCCUPATIONAL SETTING, EXPOSURE TO ZOFRAN TABLETS SHOULD BE MEDICALLY EVALUATED DURING PREGNANCY/NURSING.

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Disposal Considerations
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Waste Disposal Methods:UNUSED PRODUCT SHOULD BE DISPOSED OF AT AN APPROVED FACILITY/DISPOSE OF IN ACCORDANCE W/LOCAL, STATE & FEDERAL REGULATIONS.

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Other Information
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